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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,877	01/31/2001	Yuping Xia	REG 710B	7958

7590

08/25/2003

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/773,877

Applicant(s)

XIA ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/9/03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5,9,13,15,17,19,21,23-27 and 38-60 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1,5,9,13,15,17,19,21,23-27 and 38-60 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

## DETAILED ACTION

### ***1. Formal Matters***

- A. Amendment A, filed 6/9/03, has been entered into the record.
- B. Claims 1, 5, 9, 13, 15, 17, 19, 21, 23-27 are were pending in this application. New claims 38-60 have been added. Therefore, claims 1, 5, 9, 13, 15, 17, 19, 21, 23-27 and 38-60 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Specification***

- A. The specification is objected to due to the use of hyperlinks, for example, on page 36, line 18. Applicant is advised that embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

### ***3. Claim Rejections - 35 USC § 112, first paragraph – lack of enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. Claims 1, 5, 9, 13, 15, 17, 19, 21, 23-27 and 38-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating tumor growth using FltD2.FltD3.FcΔC1(a) and for treating psoriatic-like focal lesions in K14VEGF transgenic mice using VEGFR1R2-FcΔC1(a), does not reasonably provide enablement for a method of using all VEGF antagonists recited in claim 1 for the treatment of psoriatic lesions, hyperproliferation of keratinocytes, epidermal hyperplasia, parakeratosis, microabscess, reteridges, infiltration of lymphocytes, or all inflammatory skin diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming methods of treating psoriasis, or of treating psoriatic lesions, hyperproliferation of keratinocytes, epidermal hyperplasia, parakeratosis, microabcess, reteridges, infiltration of lymphocytes, or all inflammatory skin diseases. Applicants have provided no guidance or working examples of using any VEGF antagonist to treat any of these diseases. Applicants have only demonstrated that FltD2.FltD3.FcΔC1(a) can treat growth of specific tumors and that VEGFR1R2-FcΔC1(a) can be used to treat psoriatic-like focal lesions in K14VEGF transgenic mice.

Applicants provide no guidance or working examples of the use of any other compounds to treat psoriasis or any causes or effects of psoriasis such as psoriatic lesions, hyperproliferation of keratinocytes, epidermal hyperplasia, parakeratosis, microabcess, reteridges, infiltration of lymphocytes. Furthermore, Applicants are not enabled for the use of the claimed VEGF antagonists for treating all inflammatory skin diseases. Furthermore, it is not predictable to one of ordinary skill in the art how to use VEGF antagonists to treat the claimed diseases.

In summary, the breadth of the claims is excessive with regard to Applicants claiming VEGF antagonists which can treat the claimed diseases. There is also a lack of guidance and working examples of the use of these antagonists to treat the claimed diseases. These factors, along with the lack of predictability to one of ordinary skill in the art as to use these compounds to treat the claimed diseases leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

#### ***4. Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1, 5, 9, 13, 15, 17, 19, 21, 23-27 and 38-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of "Flt" are not known, nor is it understood what "1(1-3)," "R->N" etc., represent. The Examiner requests Applicants point out specifically in the specification how the antagonists of claim 1 are defined.

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**5. Conclusion**

A. No claim is allowable.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
August 22, 2003

  
**ROBERT LANDSMAN**  
**PATENT EXAMINER**